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13. ABSTRACT (Maximum 200 words) Soldiers wearing protective respirators must contend with the burden the equipment places on their respiratory systems. Breathing resistance is imposed by the purifying canister, the inhalation and exhalation valves, and the internal flow path. Static pulmonary function tests performed on 23 military volunteers, 21 - 32 years old, wearing the M40 respirator without canister showed only two of seven specific pulmonary function measurements (PIF and PEF) to be statistically, significantly decreased (79% and 83% of Control, respectively). Attaching the canister resulted in these flow measurements further decreasing to 76% and 79% of Control. Maximum Voluntary Ventilation significantly decreased only for the M40 with canister (71% of Control), while it was 92% of Control for the M40 with canister. The remaining flow and volume measurements were not significantly changed.				
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PREFACE

The work described in this report was authorized under Project No. F9JB-05-001. This work was started in May 1989 and completed in June 1989.

In conducting the research described in this report, the investigators adhered to Army Regulation 70-25, Research and Development--Use of Volunteers as Subjects of Research, dated 3 July 1974, as promulgated by the Office of the Surgeon General, Department of the Army. The use of human subjects was approved by The Surgeon General's Human Subjects Research Review Board (Protocol No. 5052).

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This report has been approved for release to the public.

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CONTENTS

	Page
1. INTRODUCTION	7
2. METHODS	7
2.1 Test Methodology	7
2.2 Test Procedures	7
2.2.1 Tests Performed	8
2.2.1.1 Flow Volume Loop Test	8
2.2.1.2 Maximal Voluntary Ventilation (MVV Maneuver)	8
2.2.2 Test Configurations	9
3. RESULTS	9
3.1 Test Data	9
3.1.1 Maximum Voluntary Ventilation (MVV)	9
3.1.2 Flow Volume Loop	9
3.1.2.1 Peak Inspiratory Flow (PIF)	9
3.1.2.2 Peak Expiratory Flow (PEF)	9
3.1.2.3 Forced Vital Capacity (FVC)	12
3.1.2.4 Forced Expiratory Volume in One Second (FEV ₁)	12
3.1.2.5 FEV ₁ /FVC Ratio	12
3.1.2.6 Forced Expiratory Flow for 25-75% Vital Capacity (FEF 25-75)	12
3.2 Data Analysis	12
4. DISCUSSION AND CONCLUSIONS	13
LITERATURE CITED	17
APPENDIX - Test Data	19

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EFFECTS OF THE M40 RESPIRATOR ON PULMONARY FUNCTION MEASUREMENTS

1. INTRODUCTION

Soldiers wearing protective respirators must contend with the burden the equipment places on their respiratory systems. Breathing resistance is imposed by the purifying canister, the valves (inhalation and exhalation), and the flow path within the mask. Additionally, the respirator increases physiological dead space affecting inhaled carbon dioxide levels and body chemistry.

Previous studies¹⁻⁴ have demonstrated the effects of resistance on such parameters as endurance, pulse rate, oxygen uptake, and body temperature under exercise scenarios. This study examined the acute effects of the M40 respirator on the pulmonary function of military subjects under static conditions and determined the changes in volume and flow parameters associated with the M40 respirator.

The objectives of this study were to:

a. Examine changes in pulmonary function measurements in a subject wearing the M40 respirator compared to an unmasked baseline measurement.

b. Establish a data base on the M40 respirator for comparison with current and future mask designs.

2. METHODS

2.1 Test Methodology.

Static pulmonary function measurements were made using three test conditions: Control (no mask), M40 respirator with canister, and M40 respirator without canister. A fourth test condition, a physiological half-mask with the valves removed (Hans-Rudolph, Model #7900) was employed to determine whether it was a more appropriate Control than the No Mask Control for evaluation of the M40 respirator. A total of seven pulmonary function parameters were measured on each of 23 military volunteers breathing into a Med-Science Model 3000 Pulmonizer. Each set of measurements made on each volunteer was randomized for the four test conditions.

2.2 Test Procedures.

All testing was conducted in the Advanced Protective Systems Integration Laboratory at Aberdeen Proving Ground, Maryland. Twenty-three military subjects (22 male and one female) were tested. All subjects were soldiers stationed at Aberdeen Proving Ground, Maryland. Characteristics of the subjects are presented in Table I.

Table 1
Subject Characteristics
(Mean + S.D.)

AGE (yr)	HEIGHT (in)	WEIGHT (lb)
24 + 3.5	69 + 3.0	162 + 24.0

Each subject was screened for any respiratory problems before being accepted for testing. All testing was performed on a Med-Science Model 3000 Pulmonizer. The Pulmonizer incorporates a wedge spirometer consisting of an electromechanical, bellows-type measuring unit. Separate transducers produce voltages proportional to flow and to volume, providing dual output of in-phase flow and volume. The flow and volume outputs are computed and recorded on an IBM Personal Computer. The Pulmonizer is a standard diagnostic machine used in hospitals for pulmonary function testing.

The M40 respirator was interfaced with the Pulmonizer by hoses connected to the inlet and outlet valves. When a canister was utilized, it was sealed with a tight-fitting plastic cover and attached to the inlet hose. All hoses were fitted into a modified Y-tube with a third port and attached to the breathing hose of the Pulmonizer.

2.2.1 Tests Performed.

The following tests were performed:

2.2.1.1 Flow Volume Loop Test.

The subject was instructed to breathe tidally for a short period (3 to 4 breaths), to inhale as deeply as possible, and then forcefully exhale as much air as possible. The test finished with one more deep inhalation.

2.2.1.2 Maximal Voluntary Ventilation (MVV Maneuver).

The subject was instructed to breathe tidally until signalled to start. He then breathed in and out as deeply and quickly as possible, exerting maximal effort, for 15 seconds.

2.2.2 Test Configurations.

Each subject performed a total of three trials in the following configurations:

- (1) Without a respirator (with noseclip).
- (2) With a physiological half mask (Hans-Rudolph).
- (3) With the M40 respirator (with canister).
- (4) With the M40 respirator (without canister)

Each subject was tested randomly three times in each configuration for the flow volume loop and MVV tests. The best trial of each set of three was used for data collection. Subjects were coached to put forth their best effort.

3. RESULTS

3.1 Test Data.

3.1.1 Maximum Voluntary Ventilation (MVV).

The MVV test measures the amount of air that the subject can move through the lungs in 1 minute (Figure 1 shows a test result from one subject). The average MVV for Control was 156 L/min. With the half mask the MVV was 148 L/min (96% of Control),* with the M40 without canister it was 141 L/min (92% of Control), and with the M40 with canister it was 110 L/min (71% of Control). See the Appendix.

3.1.2 Flow Volume Loop.

The flow volume loop plots flow (liters per second) against volume (liters). Figure 2 shows an actual test result. Several parameters were measured by the flow volume loop as outlined below.

3.1.2.1 Peak Inspiratory Flow (PIF).

The average PIF for the Control was 355 L/min, for the half mask 337 L/min (98% of Control), for the M40 without canister 284 L/min (78% of Control), and for the M40 with canister 247 L/min (76% of Control).

3.1.2.2 Peak Expiratory Flow (PEF).

The average PEF was 521 L/min for Control, 403 L/min (78% of Control) for the half mask, 427 L/min (83% of Control) for the M40 without canister, and 404 L/min (79% of Control) for the M40 with canister.

*Percentage reductions are based on the mean of the individual percentages for each measurement.

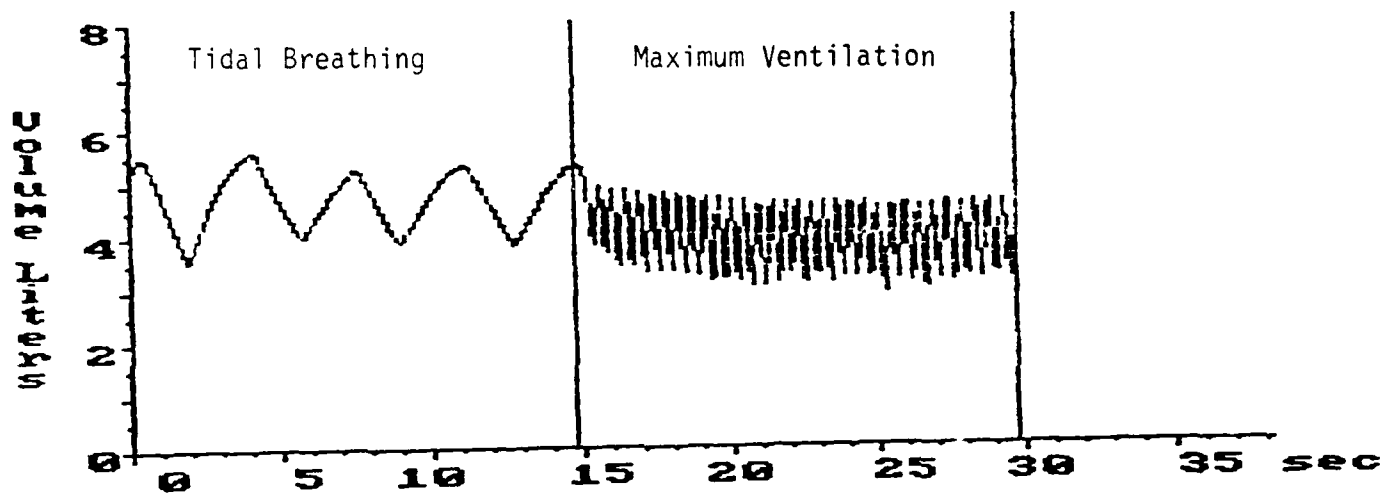


Figure 1. Maximum Voluntary Ventilation (MVV) Test Graph. An actual test result is shown. The subject was breathing tidally and when signalled began the maximum ventilation which continued for 15 seconds.

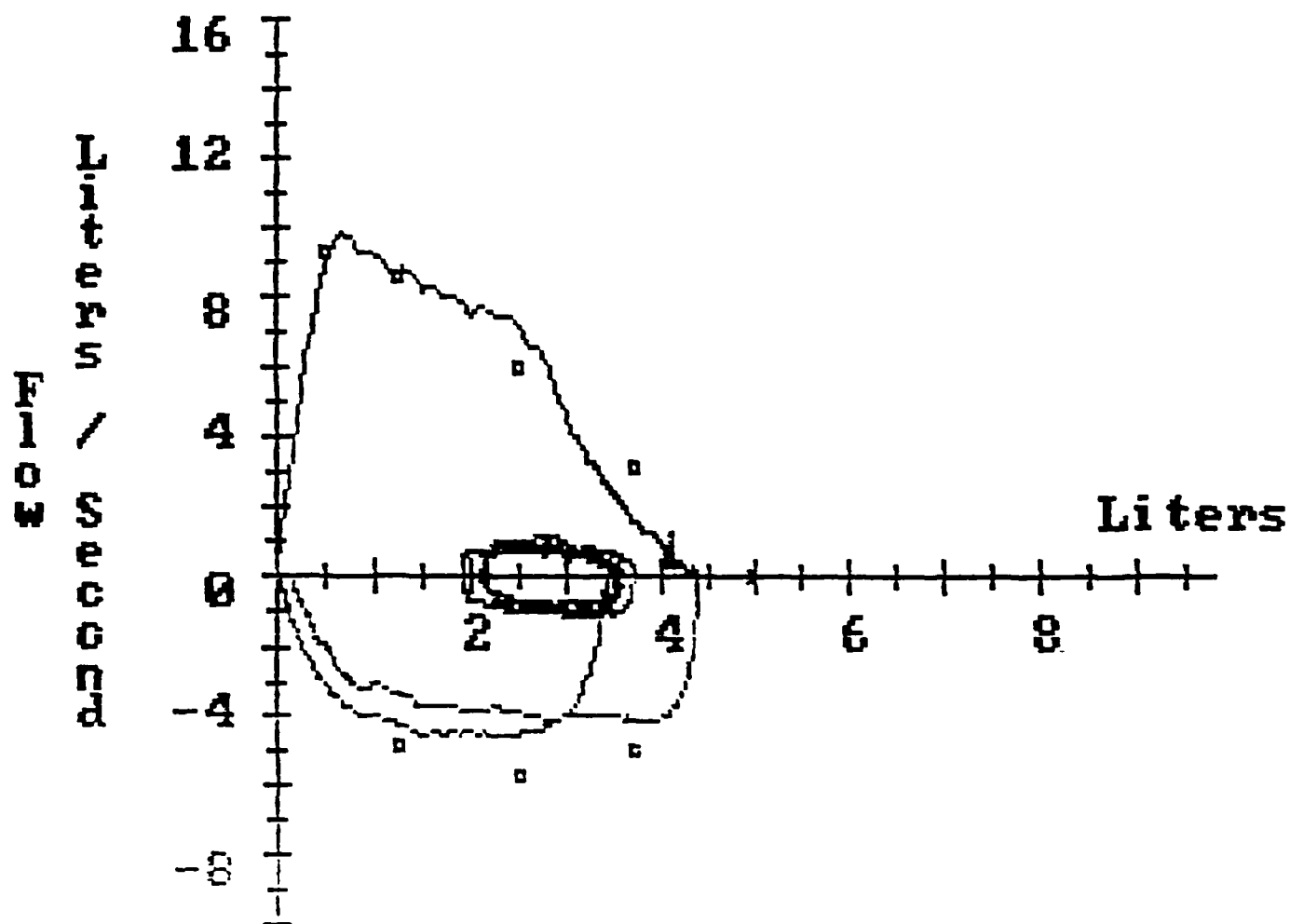


Figure 2. Flow Volume Loop Test Graph. An actual test result is shown. The small loop shows tidal breathing. The subject inhales and forcefully empties his lungs. The loop is completed with another deep breath. The small squares around the loop show predicted values for the subject based on age, height, weight, and sex.

3.1.2.3 Forced Vital Capacity (FVC).

The average FVC for Control was 4.57 L. The FVC with the half mask was 4.38 L or 96% of Control; M40 without canister, 4.49 L or 98% of Control; and M40 with canister, 4.43 L or 98% of Control.

3.1.2.4 Forced Expiratory Volume in One Second (FEV₁).

The average FEV₁ for the Control was 3.96 L. The half mask was 3.72 L or 94% of Control, the M40 without canister was 3.82 L or 97% of Control, and the M40 with canister was 3.73 L or 95% of Control.

3.1.2.5 FEV₁/FVC Ratio.

The average FEV₁/FVC was 85% for Control, with the half mask 86%, with the M40 without canister 85%, and with the M40 with canister 86%.

3.1.2.6 Forced Expiratory Flow for 25-75% Vital Capacity (FEF 25-75).

The average FEF 25-75 was 4.63 L/sec⁻¹ Control, with the half mask 4.12 L/sec⁻¹ (92% of Control), M40 without canister 4.3 L/sec⁻¹ (94% of Control), and the M40 with canister 4.08 L/sec⁻¹ (90% of Control).

3.2 Data Analysis.

Each pulmonary function measurement with the volunteer wearing the M40 respirator without and with the canister was individually paired with his/her Control; the half mask also was separately paired with the Control. Means and standard deviations for the 23 volunteers were calculated for each measurement and test condition. Power calculations using the standard errors associated with each pulmonary function measurement for the M40 respirator without and with canister were made to determine the minimum number of volunteers required for performing the static pulmonary function tests. The percent of Control [mean + standard error (S.E.)] was calculated for both M40 respirator test conditions as well as for the half mask.

These measurements were not independent of each other; thus, significance of the test results was determined by comparing the percent change from control for the M40 and the half masks. The most appropriate statistical test employs the Maximum Absolute Value of the Multivariate Student t distribution using the Upper 95% Confidence bound. A one-tailed upper bound comparison was used for the statistical analysis where d = the true difference between the mask and control, and significance results when $d < 0.99$ with nonsignificance demonstrated for $d > 1.00$. When the mask calculated Upper 95% Confidence Bound is 1.00 or more compared to control, the test data includes the control and, therefore, cannot be significantly different from control. Using the correct table for calculations of this upper bound, the Joint 95% Upper Confidence Bound = % Control Mean + 2.956 S.E. for the M40 test conditions and % Control Mean + 2.691 S.E. for the half mask.

The PIF measurements for the M40 respirator without canister were statistically analyzed for 20 of the 23 subjects. Three outliers with values of 140.4, 147.1, and 190.1% of Control were rejected for analysis because these flows represent substantial improvement over Control that fell outside the 95% confidence limit; reductions in PIF are expected as demonstrated by the mean of 78.3% of Control (See Table 2).

The static pulmonary function measurements for the M40 respirator without and with canister compared to Control (no mask) are presented in Table 2. For the M40 without canister, peak inspiratory and expiratory flows (PIF and PEF) decreased to 78.3% and 82.7% of Control respectively, significant at $p < 0.05$. The MVV for the M40 without canister decreased to 91.5% of Control, a nonsignificant change. Attaching the canister to the M40 decreased PIF and PEF further to 75.8% and 79.0% of Control ($p < 0.05$). Maximal Voluntary Ventilation (MVV) decreased to 71.1% of Control ($p < 0.05$). The remaining four pulmonary function measurements for the two M40 test conditions were not significantly different from Control.

4. DISCUSSION AND CONCLUSIONS

Measurements were also made using the half mask with no valves to evaluate whether it would be a more appropriate control than the no mask control. Selection of the Hans-Rudolph mask was considered since noseclips are not worn as is the case with the M40 respirator. Noseclips are worn with the No Mask Control. With the volunteer wearing the Hans-Rudolph, three pulmonary function measurements (PEF, FVC, and FEV₁) were significantly decreased ($p < 0.05$) compared to Control. For each of these three pulmonary function measurements, the half mask had larger percentage decreases compared to Control than did the M40 both without and with the canister. The reason for these differences cannot be explained; therefore, it was decided that the half mask is not appropriate to use as a substitute for the No Mask Control.

The flow determinations obtained showed mean MVV's of 110 and 141 L/min, PIF's of 247 and 284 L/min and PEF's of 404 and 427 L/min with and without canister respectively. Thus, although use of the M40 respirator may limit the maximum capability of the soldier in the field, these flow rates are sufficiently large to provide adequate physiologic function. Therefore, the limited statistically significant decrements in function may not be of practical importance.

Table 2
Statistical Analysis of Static Pulmonary
Function Tests (23 Subjects)

<u>Function</u>	<u>No Mask(Control)</u>	<u>Half Mask</u>	<u>M40 w/o Canister</u>	<u>M40 w/Canister</u>
MVV (l/min) (M \pm S.D.)	155.79 \pm 26.93	148.43 \pm 20.89	140.76 \pm 22.39	110.22 \pm 26.20
% Control (M \pm S.E.)	-----	96.3 \pm 2.25	91.5 \pm 2.94	71.1 \pm 2.75
Joint 95% Upper Confid. Bound*	-----	1.024	1.002	0.792 (S)
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PIF (l/sec)	5.91 \pm 1.88	5.62 \pm 1.73	4.74 \pm 1.49 (20)**	4.11 \pm 1.03
% Control (M \pm S.E.)	-----	97.8 \pm 4.73	78.3 \pm 4.38 (20)	75.8 \pm 5.52
Joint 95% Upper Confid. Bound	-----	1.105	0.912 (S)	0.921 (S)
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PEF (l/sec)	8.68 \pm 1.72	6.72 \pm 1.57	7.11 \pm 1.75	6.74 \pm 1.28
% Control (M \pm S.E.)	-----	78.0 \pm 3.02	82.7 \pm 3.92	79.0 \pm 3.21
Joint 95% Upper Confid. Bound	-----	0.061 (S)	0.943 (S)	0.885 (S)
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FVC (liters)	4.57 \pm 0.86	4.38 \pm 0.81	4.49 \pm 0.81	4.43 \pm 0.72
% Control (M \pm S.E.)	-----	95.9 \pm 1.16	98.4 \pm 1.02	97.6 \pm 1.14
Joint 95% Upper Confid. Bound	-----	0.990 (S)	1.014	1.010
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* d = true difference between Mask and Control, $d \leq 0.999$ Significant, ($p < 0.05$)
Joint 95% Upper Confidence Bound = % Control Mean + 2.956 S.E. (M40) and
% Control Mean + 2.691 S.E. (Half Mask)

**Note: PIF for M40 w/o canister - deleted 3 outlyers: 190.1%, 147.1% and
140.4% of Control

Table 2 (continued)

<u>Function</u>	<u>No Mask(Control)</u>	<u>Half Mask</u>	<u>M40 w/o Canister</u>	<u>M40 w/Canister</u>
FEF 25-75 (l/sec)	4.63 \pm 0.98	4.12 \pm 1.04	4.30 \pm 1.16	4.08 \pm 1.03
% Control (M \pm S.E.)	-----	91.8 \pm 4.34	93.6 \pm 4.07	89.9 \pm 4.13
Joint 95% Upper Confid. Bound	-----	1.035	1.056	1.021
FEV ₁ (liters)	3.96 \pm 0.60	3.72 \pm 0.61	3.83 \pm 0.64	3.73 \pm 0.50
% Control (M \pm S.E.)	-----	94.1 \pm 1.70	96.8 \pm 1.59	94.9 \pm 1.83
Joint 95% Upper Confid. Bound	-----	0.987 (S)	1.015	1.003
FEV ₁ /FVC (%)	86.4 \pm 6.58	85.2 \pm 6.61	86.4 \pm 8.15	85.2 \pm 8.32
% Control (M \pm S.E.)	-----	98.7 \pm 1.19	100.0 \pm 1.61	98.6 \pm 1.48
Joint 95% Upper Confid. Bound	-----	1.019	1.048	1.030

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APPENDIX
TEST DATA

MAXIMUM VOLUNTARY VENTILATION (MVV)

	<u>No Mask (Control)</u> <u>(liters/min)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	109.86	93.3	87.7	65.8
2	94.57	132.7	134.5	91.9
3	128.90	95.9	111.0	93.4
4	188.80	71.7	94.9	56.3
5	186.40	97.7	83.1	52.7
6	113.39	103.6	102.5	52.8
7	144.16	104.0	86.1	66.8
8	160.87	86.5	96.8	65.8
9	152.80	99.6	78.2	74.8
10	151.36	93.1	72.5	64.9
11	158.37	93.4	94.1	94.1
12	189.00	90.7	86.7	69.4
13	145.80	101.7	81.7	54.7
14	150.28	97.0	95.8	70.0
15	155.58	103.7	89.4	64.7
16	177.13	90.0	95.4	78.9
17	125.11	99.4	108.9	81.5
18	179.35	95.5	88.7	83.8
19	170.73	102.3	72.2	75.6
20	187.84	96.5	84.9	62.1
21	178.96	88.9	89.0	89.7
22	158.68	87.5	71.4	49.3
23	175.24	82.4	99.9	75.9
MEAN	155.79	96.3	91.5	71.08
STD+ _	26.93	10.8	14.1	13.20

PEAK INSPIRATORY FLOW (PIF)

	<u>No Mask (Control)</u> <u>(liters/sec)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	5.33	81.2	72.4	84.0
2	3.05	164.9	190.1	149.1
3	4.76	66.1	56.7	79.6
4	7.31	101.0	52.3	38.8
5	9.28	101.7	44.6	24.5
6	4.65	89.4	62.1	83.8
7	3.15	84.7	66.9	81.2
8	9.29	72.5	79.2	76.8
9	6.03	97.5	93.8	63.0
10	2.63	125.0	147.1	109.8
11	4.94	68.4	76.5	82.3
12	7.22	100.0	95.4	60.2
13	7.79	106.9	62.7	37.2
14	6.23	101.7	87.1	73.1
15	4.58	136.4	90.3	91.9
16	8.51	78.3	71.4	61.4
17	4.86	111.7	116.2	89.3
18	7.35	77.4	99.4	66.2
19	7.05	79.1	140.4	75.4
20	6.20	100.0	81.6	54.1
21	4.47	94.1	116.5	106.4
22	6.66	108.8	66.3	59.7
23	4.60	103.2	73.6	97.6
MEAN	5.91	97.8	88.8	75.8
STD+	1.88	22.7	34.2	26.5

PEAK EXPIRATORY FLOW (PEF)

	<u>No Mask (Control)</u> <u>(liters/sec)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	7.42	69.8	47.0	63.8
2	6.57	91.1	87.8	104.5
3	8.55	49.5	79.4	79.8
4	8.96	75.7	96.6	92.4
5	10.78	84.1	97.2	61.1
6	7.13	81.0	94.2	82.6
7	7.85	72.6	68.4	78.3
8	7.97	93.2	97.3	84.0
9	11.03	78.1	67.1	71.1
10	7.16	104.6	103.0	110.6
11	5.34	78.8	52.4	77.5
12	7.11	107.1	111.3	102.5
13	9.27	84.0	85.9	66.7
14	9.45	70.0	69.3	79.6
15	11.01	74.5	84.7	75.2
16	11.31	72.9	54.7	62.5
17	7.74	70.1	85.1	93.7
18	9.08	90.3	97.5	87.0
19	11.23	58.5	61.5	48.7
20	9.86	96.9	94.4	92.4
21	6.24	62.8	117.7	68.5
22	8.84	69.1	75.0	65.3
23	9.90	60.3	75.4	69.8
MEAN	8.68	78.0	82.7	79.0
STD \pm	1.72	14.5	18.8	15.4

FORCED EXPIRATORY FLOW IN FIRST SECOND (FEV₁)

	<u>No Mask (Control)</u> <u>(liters)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	3.34	85.0	86.5	100.2
2	3.70	100.5	97.5	97.2
3	4.09	93.1	102.4	94.3
4	4.29	93.7	92.3	91.1
5	4.70	96.1	98.7	98.2
6	3.62	96.1	98.8	101.9
7	3.34	103.5	104.4	101.4
8	5.28	92.8	96.5	76.7
9	3.74	100.5	100.8	106.1
10	3.56	101.6	101.6	100.8
11	3.13	81.4	76.9	84.0
12	3.54	100.5	99.7	103.1
13	3.66	98.3	88.2	87.1
14	4.69	94.2	100.2	102.5
15	3.58	99.4	98.6	98.0
16	4.07	99.0	98.5	99.0
17	4.12	101.6	100.7	101.6
18	4.54	99.1	98.2	97.1
19	5.14	84.0	93.1	72.5
20	4.06	95.3	103.6	97.2
21	3.52	73.5	100.2	91.7
22	3.19	95.9	108.1	97.8
23	4.07	78.3	79.3	82.8
MEAN	3.72	94.0	96.7	94.8
STD _±	.61	81.2	7.6	8.7

FORCED EXPIRATORY FLOW AT 25-75% (FEF 2575)

	<u>No Mask (Control)</u> <u>(liters/sec)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	2.84	86.6	85.5	110.2
2	3.11	114.1	98.0	99.3
3	5.14	74.9	104.8	81.5
4	7.04	91.0	84.8	90.3
5	4.57	108.5	118.5	119.4
6	3.87	96.8	96.6	100.7
7	4.79	89.5	87.4	88.9
8	5.06	118.7	98.2	64.2
9	5.18	103.2	92.2	107.5
10	3.74	106.6	101.3	100.8
11	4.33	72.0	50.1	76.6
12	5.67	99.6	113.2	106.8
13	3.65	105.7	58.6	77.8
14	3.87	103.1	106.7	110.8
15	3.59	99.1	118.9	99.4
16	4.90	106.3	99.5	95.7
17	3.88	106.7	111.0	112.6
18	4.79	100.6	91.4	92.4
19	5.08	70.8	97.6	58.4
20	4.88	106.3	108.4	101.6
21	5.17	45.0	96.7	60.1
22	5.14	66.5	89.8	66.3
23	6.26	41.0	44.4	48.4
MEAN	4.63	91.8	93.6	89.9
STD ₊	.98	20.8	19.5	19.8

FORCED VITAL CAPACITY (FVC)

	<u>No Mask (Control)</u> <u>(liters)</u>	<u>Half Mask</u> <u>(% Control)</u>	<u>M40 w/o Canister</u> <u>(% Control)</u>	<u>M40 w/Canister</u> <u>(% Control)</u>
<u>Subject</u>				
1	4.30	83.9	102.5	100.0
2	4.86	93.6	98.9	96.5
3	4.42	99.3	102.9	100.9
4	4.29	95.8	100.0	94.8
5	5.49	90.3	89.4	87.0
6	3.93	96.9	101.0	105.3
7	3.74	100.2	103.2	99.7
8	6.48	93.0	97.0	84.7
9	4.13	97.0	101.4	103.1
10	4.21	99.2	100.0	97.8
11	3.45	87.5	96.2	88.6
12	3.81	99.7	97.3	99.4
13	4.22	98.5	90.5	94.5
14	6.28	92.3	99.6	98.2
15	4.26	101.8	87.5	99.5
16	4.67	97.6	99.5	100.4
17	5.09	102.9	99.2	99.2
18	5.31	99.4	101.8	100.3
19	6.12	95.5	92.4	92.6
20	4.65	92.4	103.2	96.5
21	3.88	85.3	100.7	101.2
22	3.30	106.9	107.2	108.1
23	4.40	98.4	93.8	97.0
MEAN	4.57	95.9	98.4	97.60
STD ₊	0.86	5.59	4.9	5.49

FEV₁/FVC (%)

	<u>No Mask (Control)</u>	<u>Half Mask</u>	<u>M40 w/o Canister</u>	<u>M40 w/Canister</u>
<u>Subject</u>				
1	77.73	78.70	65.41	77.98
2	76.16	81.87	75.01	76.72
3	92.53	86.79	92.00	97.70
4	100.00	97.78	95.08	99.73
5	85.53	91.11	94.48	96.67
6	92.18	91.34	90.25	89.01
7	89.20	92.22	90.42	90.96
8	81.43	81.31	81.20	73.85
9	90.63	93.64	89.95	92.99
10	84.47	86.74	86.06	87.09
11	90.75	84.30	72.77	85.96
12	92.97	93.81	95.18	96.46
13	86.70	86.55	84.46	79.89
14	74.65	76.14	75.08	77.94
15	83.98	81.96	94.40	82.84
16	87.09	88.46	86.30	85.96
17	81.02	79.88	82.24	82.93
18	82.40	85.35	85.46	82.76
19	84.76	73.95	84.06	65.81
20	87.84	89.84	87.24	88.02
21	90.26	78.31	90.76	82.04
22	97.49	86.71	96.93	87.21
23	78.12	73.72	92.39	79.07
MEAN	86.43	85.20	86.39	85.19
STD ₊	6.58	6.61	8.15	8.32